CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 064208

Trade Name: CYCLOSPORINE USP (NONSTERILE, BULK)

Generic Name: Cyclosporine USP)Non Sterile, Bulk)

Sponsor : Abbott Laboratories

Approval Date: October 31, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 064208

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				
Approvable Letter				
Final Printed Labeling				
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)				
Administrative Document(s)				
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 064208

APPROVAL LETTER

AADA 64-208

OCT 31 1997

Abbott Laboratories
Pharmaceutical Products Division
Attention: Rebecca A. Welch
Dept. 491, Bldg. AP6B-1SW
100 Abbott Park Road
Abbott Park, IL 60064-3500

Dear Madam:

This is in reference to your abbreviated antibiotic application dated February 28, 1997, submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act, for Cyclosporine, USP (non-sterile, bulk).

Reference is also made to your amendments dated May 22, and September 25, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is acceptable for manufacturing, processing or repacking, as defined in this application. Accordingly, the application is approved.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

/S/ 10/31/97

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 064208

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

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1. **CHEMIST'S REVIEW NO.** 1A

2. **AADA#** 64-208

3. **NAME AND ADDRESS OF APPLICANT**
   Abbott Laboratories
   100 Abbott Park Road
   Abbott Park, IL 60064-3500

4. **LEGAL BASIS FOR AADA SUBMISSION**
   21 CFR §448.23

5. **SUPPLEMENT(s)**
   N/A

6. **PROPRIETARY NAME**
   N/A

7. **NONPROPRIETARY NAME**
   Cyclosporine USP

8. **SUPPLEMENT(s) PROVIDE(s) FOR**
   N/A

9. **AMENDMENTS AND OTHER DATES**
   Firm:
   Original Submission: 2/28/97
   Amendment: 5/22/97
   Fax Amendment: 9/25/97

   FDA:
   Refusal to File: 4/22/97
   Acceptable for Filing: 5/23/97
   Deficiency Letter (fax): 8/26/97

Additional Information

10. **PHARMACOLOGICAL CATEGORY**
    Immunosuppressive

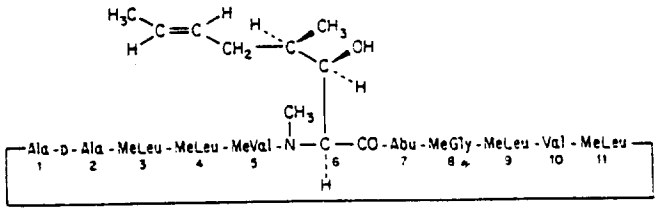
11. **HOW DISPENSED**
    For manufacturing use only

12. **RELATED IND/NDA/DMFs**
    N/A

13. **DOSAGE FORM**
Bulk drug (non-sterile)

14. **POTENCY**
98.5% to 101.5% on the dried basis

15. **CHEMICAL NAME AND STRUCTURE**



[*R*-[*R**,*R**-(*E*)]]-Cyclic(L-alanyl-D-alanyl-*N*-methyl-L-leucyl-*N*-methyl-L-leucyl-*N*-methyl-L-valyl-3-hydroxy-*N*,4-dimethyl-L-2-amino-6-otenoyl-L-α-aminobutyryl-*N*-methylglycyl-*N*-methyl-L-leucyl-L-valyl-*N*-methyl-L-leucyl)

$C_{62}H_{111}N_{11}O_{12}$
Molecular Weight: 1202.64

16. **RECORDS AND REPORTS**
N/A

17. **COMMENTS**
All CMC deficiencies were adequately addressed in the firm's 9/25/97 fax amendment. Lab results remain pending.

18. **CONCLUSIONS/RECOMMENDATIONS**
Approval is recommended (pending acceptable lab results) > Results found acceptable as of 10/16/97

19. **REVIEWER** /S/
Susan Rosencrance 10/1/97

DATE COMPLETED
10/1/97

/S/